K120028

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510(k) SUMMARY

Submitter Information

Company:	PEGAVISION CORPORATION 2F-1 No.5, Shing Yeh St. Shan Ding Vil. Kwei Shan Hsiang, Taoyuan Hsien 333, Taiwan
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Date Prepared:	Dec. 27, 2011

Identification of Device

Trade Name:	Aquamax (Etafilcon A) Bi-Weekly Disposable Soft (Hydrophilic) Contact Lenses Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses
Common Name:	Soft (hydrophilic) Contact Lenses (daily wear)
Classification Name:	Lenses, Soft Contact, Daily Wear 21CFR. 886.5925, Product Code LPL Lenses, Soft Contact (Disposable), 21CFR. 886.5925, Product Code MVN
FDA Classification:	Class II

Indication for use

1. PEGAVISION Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for vision correction of refractive ametropia in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit refractive astigmatism of 2.00 diopters (D) or less where the astigmatism does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from

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0.00D to -12.00D. Eye Care Practitioners may prescribe the lens for single-use daily disposable wear. The lens is intended for single-use disposable wear.

2. PEGAVISION Aquamax (Etafilcon A) Bi-weekly Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for vision correction of refractive ametropia in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit refractive astigmatism of 2.00 diopters (D) or less where the astigmatism does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from 0.00D to -12.00D. The lens is intended for frequent/planned replacement wear with cleaning, rinsing, disinfection and scheduled replacement as prescribed by the eye care professional. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical (not heat) lens care system only.

Description of Device

Aquamax (Etafilcon A) Bi-Weekly Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are available as spherical lenses manufactured by cast molding method. The model illuminated with high water (58 %). These hydrogel lens materials are random copolymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which were crosslinked with ethylene glycol dimethacrylate (EGDMA) and 1,1,1-trimethylolpropane trimethacrylate (TMPTMA) via photo-polymerization. These lenses are tinted blue using C.I. reactive blue 19 to make them more visible for handling. These lenses contain UV blocker, a benzotriazole UV absorbing monomer to block UV radiation. The average transmittance characteristics of theses lenses are less than 5 % in the UV range of 280-315 nm and less than 30% in the UVA range of 315-380nm. Lenses are supplied sterile in sealed blister package containing sterile isotonic borate buffered saline solution.

Summary of Clinical Study

Etafilcon A lenses have been used widely. Its safety and effectiveness have been well documented. Their safety and effectiveness can be further exemplified by two lenses cleared by FDA

- ACUVUE (Etafilcona A) Contact lens, clear and visibility tint with UV blocker, K

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962808 Submitted by Vistakon USA

- Discon Plus (Etafilcon A) Contact Lens, visibility tint with UV blocker, K083288, submitted by Innova Vision, Taiwan.

Clinical studies for Aquamx Bi-Weekly Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are not required for the premarket notification as the USAN name and process are the same as the above mentioned predicate devices.

Non-clinical Study

All tests were conducted in accordance with the May 1994 FDA guideline title Premarket Notification 510(K) Guidance Document for Class IV Contact Lenses.

The non-clinical performance tests had been performed to demonstrate the safety and effectiveness of Aquamax (Etafilcon A) Bi-Weekly Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and establish substantial equivalence to predicate lenses ACUVUE Contact Lens clear and visibility tint with UV blocker (K962804); and Discon Plus Contact Lens visibility tint with UV Blocker. The evidence of substantial equivalence to the predicate lenses is described below.

a) Technological characteristics studies

The technological characteristics of Aquamax (Etafilcon A) Bi-Weekly Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are illustrated in the following Table.

Characteristic	Aquamax (Etafilcon A) Bi-Weekly Disposable Soft (Hydrophilic) Contact Lenses	Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses	ACUVUE (K962804)	Discon Plus (K083288)
FDA Group	Group IV > 50 % water, ionic polymer	Group IV > 50 % water, ionic polymer	Group IV > 50 % water ionic polymer	Group IV > 50 % water ionic polymer
USAN Name	Etafilcon A	Etafilcon A	Etafilcon A	Etafilcon A
Production Method	Cast molding	Cast molding	Cast molding	Cast molding

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Characteristic	Aquamax (Etafilcon A) Bi-Weekly Disposable Soft (Hydrophilic) Contact Lenses	Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses	ACUVUE (K962804)	Discon Plus (K083288)
Water content	58 %	58 %	58 %	58 %
Refractive Index	1.402	1.402	1.40	1.407
Oxygen permeability (edge corrected)) @35 °C	19.3×10^{-11} (cm^2/sec)(mL O_2/mL-mmHg)	19.3×10^{-11} (cm^2/sec)(mL O_2/mL-mmHg)	26×10^{-11} (cm^2/sec)(mL O_2/mL-mmHg)	24×10^{-11} (cm^2/sec)(mL O_2/mL-mmHg)
Power(Diopter)	0.00 to -12.00 D	00.00 to -12.00 D	+ 20.00 to -20.00D	+ 20.00 to -20.00D
% transmittance:				
% T at 593 nm	>95 %	>95 %	>85 %	>93 %
% T at 380-315 nm	<30 %	<30 %	<30 %	<30 %
% T at 315-280 nm	< 5 %	<5 %	<5 %	<5 %

The oxygen permeability data for predicate lenses were copied from 510(K) summary of respective lens. Actual measurement of oxygen permeability for ACUVUE gave substantially equivalent value within error of measurement.

b) Biocompatibility

The standard cytotoxicity, maximization sensitization and ocular irritation tests were carried out for both Aquamax (Etafilcon A) Bi-Weekly Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and negative responses were recorded for all tests. The validity of blister package for lenses was demonstrated by passing the standard extraction tests.

c) Microbiology

Steam sterilization process had been validated to deliver a minimum SAL of 10^{-6}, thereby complying with the requirement of FDA group IV. There is shelf-life stability supporting that these lenses remain sterile through the expiration date claimed for the product

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d) Bacteriostatic Validation

The steam sterilizer was tested for effectiveness by measuring and demonstrating the uniformity of temperature at different location inside the sterilizer over test period. Tested microorganisms were killed under tested conditions as compared to control.

Lenses remained sterilized and there was no microbial growth for a period of 5 years tested under accelerated condition. Seal of lens packages remained tight for a period of 5 years as demonstrated by the constant peeling strength tested under accelerated condition.

e) Leachability

Studies were conducted to determine the leachable materials from the finished lenses. The results show that, at the levels of the detection reported, there are no leachable monomers and additive residues.

Substantial Equivalence Statement

In conclusion, it is PEGAVISION's conviction that data submitted in this 510(K) to validate the claim of substantial equivalency, substantiates our ability to manufacture soft contact lenses, the Aquamax (Etafilcon A) Bi-Weekly Disposable Soft (Hydrophilic) Contact Lenses and Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses, with the same established safety profile and effectiveness as the predicate devices – ACUVUE (Etafilcon A) Contact Lens clear and visibility tint with UV blocker cleared via K962804; and Discon Plus Contact Lens visibility tint with UV Blocker cleared via K083288.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Pegavision Corporation
c/o Mr. Tony Hsu
President
2F-1 No.5, Shing Yeh St. Shan Ding Vil. Kwei Shan Hsiang,
Taoyuan Hsien 333, Taiwan

Re: K120028
Trade/Device Name: Aquamax (Etafilcon A) Disposable Soft (Hydrophilic) Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Codes: LPL, MVN
Dated: March 8, 2012
Received: March 12, 2012

Dear Mr. Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jessica Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K120028

Device Name: PEGAVISION Aquamax (Etafilcon A) Disposable Soft (Hydrophilic) Contact Lenses

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Prescription Use X **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marc Robboy

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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